K061912

Fusion 510(k) Summary

AUG 0 1 2006

Submitter's Name & Address:

Burke, Inc.
1800 Merriam Lane
Kansas City, KS 66[illegible]
Phone: 913-722-565[illegible]
Fax: 913-722-2614

Contact Person:

DuWayne E Kramer
Official Correspondent

Date Prepared:

06-22-06

Name of Device and Proprietary Name:

Fusion

Common or Usual Name:

3 Wheel Power Scooter

Class:

II

Classification Name:

Vehicle, Motorized 3-Wheeled

Product Code:

INI

Device Description:
The Fusion is an indoor/outdoor scooter that is battery operated. Fusion uses all our standard technology seating, thumb operated throttle, digital controller, charger, motor, brake, transaxle, frame material and till we have used for years on our PaceSaver units. The Fusion frame separates for transport and has removable batteries and seat. Accessories include a front light and a basket.

Comparison to Predicate Devices:
The Fusion is substantially equivalent to our PaceSaver Little Junior (K[illegible]122) and PaceSaver Espree Scooter (K965123) when comparing maneuverability, stability, performance and technological characteristics. While the frame material is the same, Fusion's key change is in the frame design. PaceSaver Fusion uses 3 primary wheels similar to the predicate device design. However, while the predicate devices use two fixed-in-place anti-tip wheels for tip-over safety, the Fusion uses two caster wheels on spring-loaded trailing arms. Fusion's patent-pending frame design provides the indoor maneuverability of our small scooter with the traction and stability of our larger standard scooters.

Intended Use:
Motorized five-wheeled battery powered scooter intended for medical purposes by disabled persons and other non-medical purposes.

Non-Clinical Testing:

Compliance with applicable Testing Standards is as follows:

ANSI/RESNA WC/01 Determination of Static Stability
ANSI/RESNA WC/02 Determination of Dynamic Stability
ANSI/RESNA WC/03 Effectiveness of Brakes
ANSI/RESNA WC/04 Determination of Energy Consumption – Theoretical Range
ANSI/RESNA WC/05 Overall Dimensions, Mass, and Turning Space
ANSI/RESNA WC/06 Determination of Maximum Speed, Acceleration, and Retardation of Electric Wheelchairs
ANSI/RESNA WC/08 Test Methods for Static, Impact, and Fatigue Strengths
ANSI/RESNA WC/09 Climatic Tests
ANSI/RESNA WC/10 Obstacle Climbing
ANSI/RESNA WC/15 Documentation and Labeling
ANSI/RESNA WC/93 Maximum Overall Dimensions

Discussion of Clinical Testing Performed:
Clinical testing is not appropriate and not required for the proposed device. Clinical testing was not performed.

Conclusions:
The PaceSaver Fusion has the same intended use and substantially equivalent technological, physical, and operational characteristics as the predicate devices PaceSaver Little Jr. (K925122) and PaceSaver Espree Scooter (K965123). Moreover, the non-clinical testing and comparison to predicate devices demonstrates that the differences do not cause any questions as to the safety or effectiveness of the proposed device. The Fusion has passed the necessary testing to recognized consensus standards and is considered to be safe for user operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2006

Burke, Inc.
% Mr. DuWayne E. Kramer, Jr.
President
1800 Merriam Lane
Kansas City, Kansas 66106

Re: K061912
Trade/Device Name: PaceSaver Fusion
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: June 30, 2006
Received: July 6, 2006

Dear Mr. Kramer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

To: Elmar Einberg
Re: K061912 Fusion

Indications for Use

510(k) Number (if known): K061912

Device Name: PaceSaver Fusion

Indications For Use:

Motorized five-wheeled battery powered scooter intended for medical purposes by disabled persons and other non-medical purposes.

Prescription Use _____ AND/OR Over-The-Counter Use _X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061912